

Exhibit H

A comparison of the plaque removal efficacy of two power toothbrushes: Oral-B Professional Care Series versus Sonicare Elite

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Aim: To compare the safety and plaque removal efficacy of an oscillating/ pulsating toothbrush (Professional Care Series, Oral-B Laboratories; PCS) and a high frequency toothbrush (Sonicare Elite, Philips Oral Healthcare; SE). **Methods:** The study had a randomised, examiner-blind, crossover design. Sixty-one subjects aged 19–64 years were enrolled. After 23–25 hours of no oral hygiene, subjects received an oral tissue examination and those with pre-brushing whole mouth mean plaque scores ≥ 0.60 measured by the Rustogi modified Navy Plaque Index were randomly assigned to treatment sequence. Subjects brushed with their assigned toothbrush for 2 minutes using a commercially available dentifrice. Oral tissues were then re-examined and post-brushing plaque scores recorded. After a brief washout period, the above procedures were repeated with the alternate toothbrush. One examiner blinded to the treatment sequence performed all clinical measurements. **Results:** All 61 subjects completed the study. Both toothbrushes significantly reduced plaque levels after a single brushing (t -test, $p < 0.0001$). However, the PCS was significantly more effective than the SE in whole mouth plaque removal and in reducing plaque from marginal, buccal, lingual and approximal surfaces (ANOVA, $p < 0.0001$). Whole mouth plaque was reduced by 88% versus 61% and approximal plaque by 97% versus 73% for the PCS and SE toothbrushes, respectively. There was no evidence of hard or soft tissue trauma after a single-use of either toothbrush. **Conclusion:** Based on the findings of this single-use clinical evaluation, the action of the oscillating/ pulsating power toothbrush is more effective at plaque removal than a high frequency power toothbrush.

Key words: Oscillating/pulsating power toothbrush, high frequency power toothbrush, plaque removal, plaque index

Since their initial introduction in the 1960s, numerous power toothbrushes have been developed and launched for commercial use. Given the considerable variation in brush head design and mode of action, it cannot be assumed that all power toothbrushes are equally effective in plaque removal efficiency or offer significant advantages over manual toothbrushing. The Oral-B range of power toothbrushes are based on a clinically

proven oscillating/rotating action. Indeed, an independent systematic review of power toothbrushes recently undertaken by the Cochrane Collaboration found only toothbrushes with a rotation oscillation movement have consistent benefits over manual brushing in plaque removal and maintenance of gingival health in both the short (less than 3 months) and long (3 months or longer) term¹.

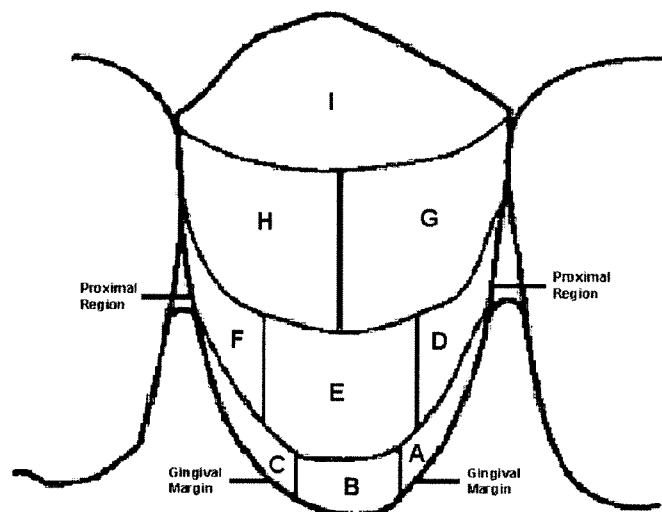


Figure 1. Rustogi Modification of Navy Plaque Index⁶. Disclosed plaque is scored in each tooth area as present (scored as 1) or absent (scores as 0) and recorded for both buccal and lingual surfaces. Tooth area plaque scores are grouped and designated as: Whole mouth = Areas A, B, C, D, E, F, G, H and I; Marginal (gumline) = Areas A, B and C only; Approximal D and F only.

Over the past decade, the Oral-B power toothbrush has undergone a series of modifications to improve plaque removal from all tooth surfaces, including hard-to-access areas such as the approximal surfaces of molars and premolars²⁻⁴. An increase in the oscillating/rotating frequency from 47Hz in the D7 model to 63Hz in the D9 model enhanced efficacy^{2,3}, as did the addition of a pulsating action of 340Hz in the D15 and D17 models⁴. Most recently, the Professional Care Series has been introduced, which has an oscillating frequency of 73Hz and a pulsating frequency of 340Hz. In contrast to the Oral-B power brush, the Sonicare Elite toothbrush has a mode of operation where the bristles vibrate in a side-to-side motion at a frequency of 260Hz⁵.

As newer models are introduced it is important to evaluate their safety and relative ability to remove plaque so that dental professionals are kept up-to-date in their recommendations to patients. The present study was designed to compare the safety and plaque removal efficacy of two power toothbrushes, the Oral-B Professional Care Series (PCS; Oral-B Laboratories, Boston, MA, US) and the Sonicare Elite (SE; Philips Oral Healthcare, Snoqualmie, WA, US) after single-brushing use. Plaque removal efficacy of these power toothbrushes was assessed by the Rustogi modified Navy Plaque Index, which permits separate evaluation of the presence of plaque in areas routinely missed by toothbrushing, such as lingual, marginal and approximal surfaces⁶.

Subjects and methods

Subjects

The study population comprised healthy subjects aged 18–70 years who had a minimum of 18 scorable teeth

(not including 3rd molars, teeth with orthodontic appliances, bridges, crowns or implants). Each subject presented with a whole mouth pre-brushing plaque score ≥ 0.6 based on the Rustogi modified Navy Plaque Index⁶ (RMNPI; Figure 1) and currently used a power toothbrush.

Subjects were excluded if they had any physical limitations or restrictions that might preclude normal oral hygiene procedures, i.e. brushing. Other reasons for exclusion included evidence of neglected dental health and major hard or soft tissue lesions at the baseline examination; use of antibiotics or anti-inflammatory medications for three consecutive days or more within the previous 28 days; and any medical condition with a requirement of prophylactic antibiotics before dental treatment. All subjects gave written informed consent and completed a medical history form. The study was conducted at a single centre (BioSci Research Canada Ltd.) and complied with current Good Clinical Practice (GCP) Guidelines.

Study design

This study had a randomised, examiner-blind, cross-over design and involved two study visits. After screening and enrolment, subjects were randomly assigned by subject number to one of two treatment sequence groups (PCS/SE or SE/PCS). Subjects refrained from oral hygiene for 23–25 hours and from eating, drinking or smoking for 4 hours preceding each study visit. All subjects brushed according to instructions provided by the manufacturer and were given sufficient time to read, understand and ask any questions about the tooth brushing technique. Each subject brushed with a controlled amount of dentifrice (Crest Cavity Protec-

tion, Procter & Gamble Company, Cincinnati, OH, USA) for 2 minutes under supervision without access to a mirror to avoid observation of disclosed plaque, which may have biased their brushing. Subjects returned to their usual method of oral hygiene for a brief washout period (minimum 4 days) and returned for a second study visit to repeat the procedure with the alternate toothbrush.

Clinical assessments

All clinical evaluations were performed by the same examiner who was unaware of the type of brush used by the subject. Pre- and post-brushing oral safety assessments involved a hard and soft oral tissue examination including the lips, tongue, gingiva, sublingual area, inner surfaces of the cheeks, mucobuccal folds, hard and soft palate, and pharyngeal area. Assessments included colour, texture, soft tissue abrasion, and any irregularities of tissue surfaces. Any abnormal findings and all adverse events were documented. Pre- and post-brushing plaque was scored using the RMNPI, which divides each of the buccal and lingual surfaces into nine areas (*Figure 1*). Plaque was disclosed following a standard procedure whereby subjects swished with 20 drops of Chrom-O-Red (Germiphene Corp., Brantford, Ontario, Canada) for 15 seconds and then rinsed with 10ml of tap water for a further 10 seconds. After disclosure, plaque was scored (absent=0, present=1) for the nine designated areas of both the buccal and lingual surfaces of each scorable tooth⁶.

Toothbrush design

The design and action of the PCS is based on the earlier D17 and D15 models^{7,8}. Briefly, the PCS has an oscillating brush head action with an oscillation angle of 45°, a frequency of 73Hz and a pulsating action in the direction of the bristle filaments of 340Hz (*Figure 2*). The brush head is 13.45mm in diameter with individual bristles 0.006" (0.1524mm) in diameter and a control system limits the brushing force by switching off the vibratory action at a preset pressure. The Sonicare Elite toothbrush operates with a side-to-side bristle action at a frequency of 260Hz, and has a brush head with a curved side profile and a neck slightly angled relative to the handle (*Figure 2*)⁹. The easy-start feature was deactivated prior to use as recommended by the manufacturer.

Statistical analysis

Using variability estimates from previous studies of this design (data on file, Oral-B Laboratories), power curves were examined to indicate the number of subjects needed to detect statistically significant treatment differences. Based on these data, assuming $\alpha =$

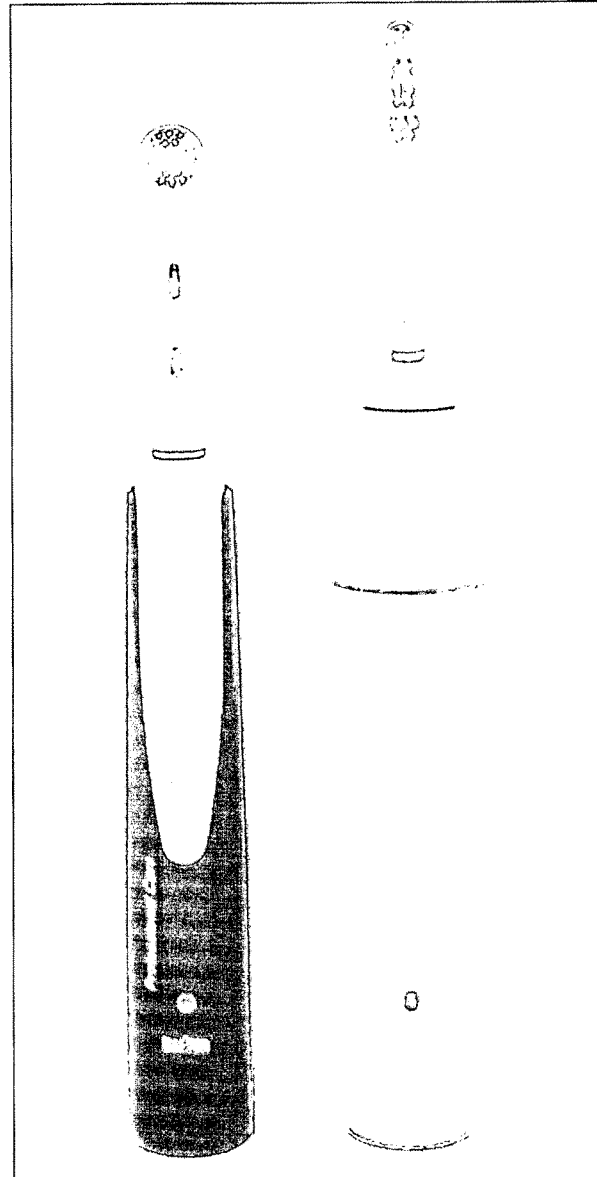


Figure 2. The Oral-B PCS toothbrush (left) and the Sonicare Elite toothbrush (right)

0.05, a sample size of 60 subjects per treatment group was needed to ensure an 80% (power = $1 - \beta$) or greater chance of detecting differences of ≥ 0.03 whole mouth RMNPI units. Baseline variables were analysed for comparability between treatment sequence groups using an analysis of variance (ANOVA). Pre- to post-use differences between products in the RMNPI score for whole mouth, buccal, lingual, marginal, and approximal surfaces were analysed using an ANOVA. Changes within each treatment group were evaluated using a paired *t*-test. All hypothesis tests were conducted at the two-sided $\alpha=0.05$ level of significance. A comparison of the proportion of oral hard and soft tissue abnormalities in the two treatment groups at each visit was conducted using a chi-square test.

Table 1 Subject demographics

	Treatment sequence group PCS/SE	Treatment sequence group SE/PCS
Number of subjects	30	31
Male/female	8/22	15/16
Mean age (years) \pm SD (range)	34.6 \pm 9.3 (19-55)	40.3 \pm 10.6 (24-64)
Mean whole mouth RMNPI – visit 1	0.63 \pm 0.03	0.63 \pm 0.03
Mean whole mouth RMNPI – visit 2	0.62 \pm 0.03	0.63 \pm 0.03

Table 2 Pre- and Post-brushing RMNPI scores (mean \pm SD)

Site	Toothbrush	Pre-brushing (\pm SD)	Post-brushing (\pm SD)	Mean plaque reduction* (\pm SD)	Percent plaque removal
Whole mouth	PCS	0.630 \pm 0.03	0.076 \pm 0.05	0.554 \pm 0.05	88.0
	SE	0.626 \pm 0.03	0.247 \pm 0.10	0.379 \pm 0.08 $p=0.0001$	60.6
Gingival margin	PCS	1.000 \pm 0.00	0.200 \pm 0.12	0.800 \pm 0.12	80.0
	SE	1.000 \pm 0.00	0.535 \pm 0.16	0.465 \pm 0.16 $p=0.0001$	46.5
Approximal	PCS	1.00 \pm 0.00	0.034 \pm 0.06	0.966 \pm 0.06	96.6
	SE	1.00 \pm 0.00	0.271 \pm 0.18	0.729 \pm 0.18 $p=0.0001$	72.9
Buccal	PCS	0.646 \pm 0.05	0.053 \pm 0.04	0.593 \pm 0.05	91.8
	SE	0.646 \pm 0.05	0.173 \pm 0.10	0.473 \pm 0.09 $p=0.0001$	73.2
Lingual	PCS	0.613 \pm 0.03	0.098 \pm 0.08	0.515 \pm 0.07	84.0
	SE	0.606 \pm 0.04	0.321 \pm 0.14	0.285 \pm 0.12 $p=0.0001$	47.1

*Mean plaque reductions within treatment groups were significant (t -test $p<0.0001$).
Group comparison by ANOVA.

Results

Study population

A total of 61 subjects were enrolled and completed the study. The study population comprised 23 males and 38 females of mean age 37.8 years (range, 19–64 years). There was no significant difference between treatment sequence groups for gender or baseline RMNPI scores, but the subjects in the PCS/SE group tended to be younger (Table 1).

Safety

No adverse events were reported during the study. There was no evidence of soft or hard tissue abrasion after single brushing with either the PCS or SE toothbrush.

Efficacy

Both the PCS and SE toothbrushes were effective in removing plaque from all tooth surfaces after a single-use. Both brushes demonstrated significant reductions in mean plaque scores from pre-brushing to post-brushing levels for whole mouth, marginal and approximal surfaces, as well as buccal, and lingual areas ($p<0.0001$; Table 2). However, comparison

between the two power toothbrushes revealed the PCS had significantly greater efficacy in plaque removal than the SE for all tooth surface areas, including marginal and approximal areas (Table 2). The mean percentage plaque removal for each surface measured is shown in Figure 3. The differences in plaque reduction in favour of the PCS versus the SE were 27.4% in whole mouth plaque, 33.5% at the gingival margin, 23.7% at approximal surfaces, 18.6% at buccal and 36.9% lingual areas (Table 2).

Discussion

Given the wide diversity in power toothbrush design and mode of operation, it can be expected that differences will exist in their ability to remove dental plaque. Comparative studies are an essential part of the clinical programme and provide dental professionals with invaluable information about the most effective models currently available. Recently, developments in power toothbrush design have resulted in the introduction of the PCS, a model founded on a clinically proven oscillatory/rotation technology¹, and the SE, a high frequency toothbrush with a side-to-side action^{5,9}.

The data from this randomised, examiner-blind, crossover study of the oscillating/rotating PCS versus

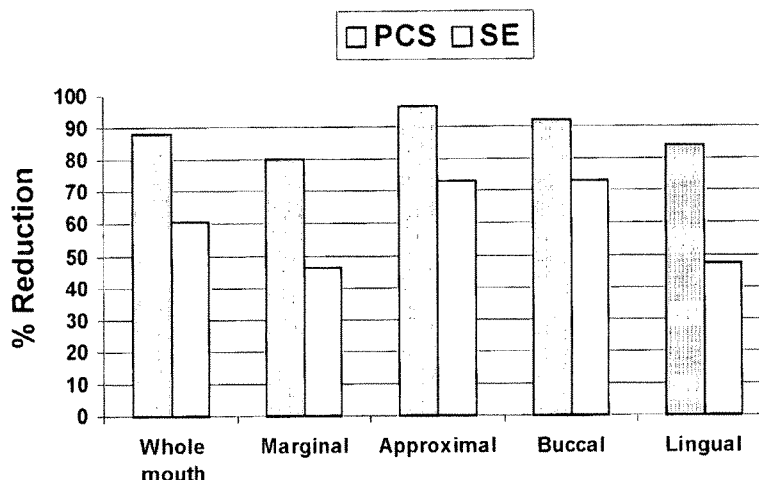


Figure 3. Plaque removal efficacy after a single brushing with the PCS or SE toothbrush

the high frequency SE showed that although both power toothbrushes were effective in removing plaque after single-use, the PCS toothbrush removed significantly more plaque. Modifications in the design of the Oral-B range of power toothbrushes have seen changes in operating frequency, brush head design and filament technology aimed towards improving plaque removal from all tooth surfaces²⁻⁴. Therefore, it was particularly relevant in the present study to use a plaque index that assessed areas most susceptible to plaque accumulation and often missed by tooth brushing, such as the gingival margin and approximal surfaces¹⁰. Changes from pre- to post-brushing Rustogi modified Navy Plaque Index scores indicated that the PCS removed significantly more plaque than the SE from all tooth surfaces, with over 20% and 30% greater plaque reduction in hard-to-reach approximal and gingival margin areas, respectively.

These findings are in agreement with several other comparative studies of the Oral-B oscillating/rotating brushes versus the Sonicare power toothbrush, where various models within the Oral-B power toothbrush range have demonstrated significant advantages over the Sonicare toothbrush with respect to plaque removal¹¹⁻¹⁴. When considering plaque scores of all measured sites, the reduction in plaque was significantly greater with the Oral-B oscillating/rotating toothbrush than the high frequency Sonicare¹¹⁻¹⁴. Comparisons across studies are difficult to make, not least because of differences in study designs and methods used to score plaque. Nevertheless when the indices allowed measurement of plaque from approximal surfaces, the results were also in favour of the oscillating/rotating brush^{11,12}.

Conclusion

Based on the findings of this single-use clinical evaluation of the most recently developed Oral-B and

Sonicare power toothbrushes, it can be concluded that the oscillating/rotating action of the Professional Care Series provides greater plaque removal efficacy than the Sonicare Elite, especially from hard-to-access approximal surfaces where plaque tends to accumulate.

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